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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,627	04/17/2001	Joseph R. Lakowicz	2542-101	3516

23373 7590 11/05/2003

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EXAMINER

SNAY, JEFFREY R

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 11/05/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,627

Applicant(s)

LAKOWICZ ET AL.

Examiner

Jeffrey R. Snay

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☒ Claim(s) 37-42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method including an analyte dependent fluorophore having a ns decay time in combination with a reference fluorophore having a longer microsecond decay time, does not reasonably provide enablement for the presently recited claims without these limitations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to perform the invention commensurate in scope with these claims.

The specification clearly establishes that the disclosed invention contemplates the discovery by applicant that monitoring the amplitude modulation at intermediate frequencies of emission from a pair of fluorophores, one an analyte responsive fluorophore and of ns decay time and the second a reference fluorophore of a longer microsecond decay time, renders the detected emission of both fluorophores to be equivalent to the fraction of the total emission of the short lifetime fluorophore. See page 3, lines 13-15, and page 5, lines 1-11 of the specification. The disclosed method thus clearly requires these limitations as to the first and second fluorophores in order to achieve the contemplated result.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 6, 10, 14, 16, 23-28 and 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Lakowicz et al (US 5246867).

Lakowicz et al disclose an analytical method comprising irradiating a sample including a first fluorophore (donor) which is responsive to the analyte and a second fluorophore (acceptor). The sample is irradiated with intensity modulated light and the emission from the sample is analysed by phase-modulation to determine the presence of the analyte of interest, such as glucose. See particularly columns 5 and 6 of Lakowicz et al. A modulation frequency of 100 MHz is disclosed (see example 6). Specific embodiments of Lakowicz et al disclose glucose sensitive fluorophores bound to concanavalin A (column 5, lines 37-42). The irradiation can be performed with an electroluminescent device (column 5, lines 20-24). The clinical diagnostic method of Lakowicz et al would have been capable of characterization as any of a bioprocessing reaction, analytical chemistry process, or industrially or process control, as presently recited in claims 33-35 respectively.

Allowable Subject Matter

4. Claims 37-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

5. Applicant's arguments filed 08-25-03 have been fully considered but they are not persuasive.

6. Applicant argues that the rejection under 35 U.S.C. 112, first paragraph, improperly requires limitation of the claims to an exemplary embodiment. The argument is not persuasive because the limitations noted in the grounds of rejection as omitted from the claims are disclosed as being required rather than merely preferred. See e.g. page 3, lines 13-15, and page 5, lines 1-11 of the specification.

7. Applicant further traverses the rejection based on prior art because the prior art method involves energy transfer between the first and second fluorophores, which is not required in the instant claims. However, energy transfer between fluorophores is not precluded by the instant claims and in fact is recited to the extent that claim 1 requires light emitted by the first fluorophore to irradiate the second fluorophore. Applicant further argues that the prior art method requires the first fluorophore to be insensitive to analyte. However, the noted disclosure in the prior art reference relates to binding insensitivity rather than emission sensitivity. The instant claims require the first fluorophore to absorb incident light in a manner which is sensitive to analyte. Such incident light absorption is clearly present and required in the prior art method in order to attain the disclosed optical analyte detection.

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Conclusion

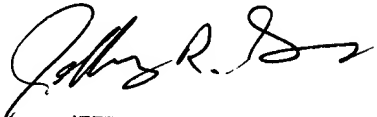
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Snay whose telephone number is (703) 308-4032. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


JEFFREY SNAY
PRIMARY EXAMINER